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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,249	08/21/2001	Richard T. Lee	P0738/7001 (ERP/KA)	6506

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EXAMINER	
LUCAS, ZACHARIAH	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/934,249	LEE ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4, 8-11, 68, 80-83, 86-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8-11,68,80-83 and 86-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Currently claims 1-4, 8-11, 68, 80-83, and 86-90 are pending and under consideration in the application.

2. In the prior action, the Final action mailed on August 23, 2005, claims 1-4, 8-11, 68, 80-83, and 86-88 were pending and rejected.

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 22, 2005 has been entered.

4. In the Response submitted on December 22, 2005, the applicant amended claims 1 and 4.

5. Applicant's arguments regarding the Finality of the prior action are noted. However, the new rejection was necessitated by the amendment of claim 89 to require that the claimed nucleotide is at least 24, as opposed to the previously claimed at least 8, 10, 12, 14, 16, 18, 20, or 22, nucleotides in length. Because the amendment changed the scope of the claim such that it was no longer subject to rejection by the Xu reference alone, but required the additional teachings of another reference, the new rejection was necessitated by the amendment.

However, in view of the submission of an RCE, the traversal of the finality of the prior action is also considered moot.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. **(Prior Rejection- Maintained)** Claims 1-4, 8-11, 68, 80-83, 86-90 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Applicant traverses the rejection on the basis that the Examiner "has conceded a function of MIVR-1 that is sufficient to support enablement of the claimed inventions, its anti-apoptotic activity, with the withdrawal of the prior utility rejection under 35 U.S.C. § 101." The Applicant further traverses the rejection of the claims on the basis of the diagnostic use of the claimed compounds (fragments of the MIVR-1 nucleic acid sequence SEQ ID NO: 1, or sequences that hybridize thereto). These arguments are not found persuasive.

With respect to the assertion that withdrawal of the rejection under 35 U.S.C. 101 is an implied admission that the Applicant is enabled for the use of MIVR-1 protein, it is noted that there are different standards applied with respect to the enablement and utility requirements. While the Applicant may have asserted a utility that meets the requirement under 35 U.S.C. § 101, this does not demonstrate that the Applicant has enabled the use of the compound even with respect to that asserted utility. See e.g., MPEP § 2107.01 IV (stating "The fact that an applicant has disclosed a specific utility for an invention and provided a credible basis supporting that specific utility does not provide a basis for concluding that the claims comply with all the

requirements of 35 U.S.C. 112, first paragraph."). In the instant case, while the anti-apoptotic activity of the protein may be specific, substantial, and credible, this does not mean that the Applicant has established that the protein may be so used.

In particular, as has been indicated in the prior actions, the application has not provided any evidence that the MIVR-1 protein is actually able to induce an anti-apoptotic activity. See e.g., Action mailed on July 13, 2004, enablement rejection of pages 4-6. Because the application provides no evidence directly correlating the presence or expression of MIVR-1 to anti-apoptotic activity, there is insufficient information to demonstrate that the protein does in fact have this activity. Thus, the application has not enabled the use of MIVR-1 as an anti-apoptotic compound, or by extension, the use of the claimed nucleic acids for diagnostics associated with the asserted anti-apoptotic activity. The Applicant's first argument in traversal is therefore not found persuasive.

With respect to the second argument in traversal, the use of the claimed nucleic acids in diagnostics for cardiac conditions, it is noted that the Applicant has provided no evidence or information linking the claimed nucleic acids or MIVR-1 to any particular condition. As no additional evidence has been provided, the rejection is maintained over the second argument in traversal for the same reasons described in the prior action.

The rejection is therefore maintained for the reasons above, and the reasons of record.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. **(Prior Rejection- Clarified and Maintained)** Claims 1, 4, 68, 81, 88, and 89 were rejected under 35 U.S.C. 102(a) as being anticipated by Xu et al., Genomics 66: 257-63 (of record in the January 2003). It is noted that the rejection was previously inadvertently indicated to be a rejection under 35 U.S.C. 102(b). However, it is noted that the Xu reference was published in June 2000, whereas the current application claims benefit to provisional application 60/227159, filed on August 22, 2000, and disclosing the claimed inventions. Thus, the rejection is clarified to be a rejection under 35 U.S.C. 102 (a).

The Applicant previously amended the claims to require that fragments according to subpart (b) of the claim have a sequence of at least 23 nucleotide. Subpart (a) of the claims has now also been amended to require that the nucleotides are at least 23 amino residues in length. However, in order to be persuasive with respect to the rejection, each of the different embodiments of the claim that read on the nucleotides of Xu must include the size limitation. While each of (a) and (b) require have the at least 23 amino acids limitation, and subpart (c) includes nucleotides differing from (a) or (b) only by code degeneracy, each of these subparts avoids the rejection. However, subpart (d) reads on any complement of (a), (b), or (c), and provides no minimum number of nucleotides present in the sequence. The rejection is therefore maintained on the basis that subpart (d) still reads on the sequences of Xu.

It is suggested that the claims be amended to require that the complements of (d) are fully complementary to the sequence of (a), (b), or (c), or that the complements are also at least 23 nucleotides in length.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. **(Prior Rejection- Maintained)** Claims 1, 4, 68, 80, 81, 88, and 89 were rejected under 35 U.S.C. 103(a) as being unpatentable over Xu as applied to claims 1, 4, 68, 81, and 88 previously, and further in view of the teachings of Kumar (U.S. 5,916,776) and Buck et al. (BioTechniques 27: 528-36). Claim 80, which reads on nucleic acids that hybridize to the complement of SEQ ID NO: 1 of at least 24 bases, are included in this rejection for substantially the same reasons as indicated with respect to claim 89 previously.

The Applicant traverses the rejection on the basis that the Xu reference does not teach a sequence with 100% identity to either of SEQ ID NOs: 1 or 3, and thus does not necessarily teach the primers of the present application. Nonetheless, the reference teaches a sequence that is identical to SEQ ID NO: 1 from between positions 522-1361- a region of about 840 nucleotides (a fragment of 62% of the length of SEQ ID NO: 1). Moreover, the sequence is identical to SEQ ID NO: 3 (the protein coding region) at positions 117-861 (86.5% of the length of SEQ ID NO: 3

and the protein sequence). Thus, while the teachings of the cited references may not render obvious probes or primers directed to the first 521 bases of SEQ ID NO: 1, or the first 116 bases of SEQ ID NO: 3, the teachings of the references do render obvious such probes and primers directed to the remaining residues as they are identical to probes and primers that would have been obvious to those of ordinary skill in the art to make and use for the detection or amplification of the PMEPA1 sequence disclosed in Xu.

It is further noted that none of the rejected claims requires the presence of the full length of either SEQ ID NO: 1 or SEQ ID NO: 3. Thus, the fact that the reference does not teach these full-length sequences does not demonstrate that the claimed fragments thereof are not obvious.

Because the combined teachings of these references render obvious a number of probes and primers that may be used to detect the sequences of SEQ ID NO: 1 or 3, in view of the identity between large fragments of these sequences and a large fragment of the sequence disclosed by Xu, the rejection is maintained.

12. **(New Rejection)** Claims 1, 4, 8-11, 80, 81, and 86-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al. as applied to claims 1, 4, 68, 80, 81, 88, and 89 above, and further in view of the teachings of Srivastava et al. (U.S. 6,566,130) and Lodish et al. (Molecular Cell Biology,3rd Ed., 1995, pages 252-57). Claims 1, 4, 68, 80, 81, 88, and 89 have been described previously. Newly rejected claims 8-11, 86, 87, and 90 are drawn to expression vectors comprising the sequences described above, wherein the sequences are operable linked to a promoter, and to host cells comprising such. It is noted that these claims are drawn to expression vectors "comprising" the sequences of the previously indicated claims.

Because the gene identified in Xu comprises sequences that meet the claim limitations as described above, and because the presently rejected claims permit the presence of additional sequences (due to the use of the open "comprising" language) a vector comprising the gene disclosed by Xu falls within the scope of the present claims.

The teachings of Xu have been described in part above. The reference teaches the identification and sequencing of the PMEPA1 gene, and its identification as an androgen regulated gene (ARG) that is expressed in prostate tumors. However, the reference does not teach the expression of the protein through use of an expression vector or host cell.

The Srivastava patent also teaches the PMEPA1 gene. While this patent is directed to teachings relating to the PMEPA1 gene, the provisional application (60/178,772) to which it claims priority also indicates that the function of the ARGs needs to be better defined for possible use in cancer diagnostics and therapy. See, provisional application 60/178,772, page 4. In addition, it is known in the art that such functional studies involve the making of recombinant vectors for gene expression and the expression of such in host cells. See e.g., Lodish, pages 256-57 (teaching that recombinant expression of proteins from expression vectors is a useful process for the determination and testing of protein function). Lodish also teaches that expression vectors are produced by linking the target gene to a promoter, and that such vectors may expressed may be produced in cells. See e.g., page 252 (teaching the use of coding sequences linked to promoters for expression in bacterial host cells).

As Xu identifies the PMEPA1 gene as an ARG that is up-regulated in prostate tumors, and The Srivastava reference suggests the determination of the function of such genes, and in view of the teachings of Lodish teaching the production of expression vectors for use in making

such determinations, those of ordinary skill in the art would have been motivated to combine these teachings to produce expression vectors comprising the gene of Xu (and host cells comprising such) for the determination and study of the PMEPA1 gene and protein function. Those of ordinary skill in the art would have had a reasonable expectation of success in the making and use of such vectors and host cells as these are routine activities in the art.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner